GP1645

Docket No.: 1414-011 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#41 (NB) linda 7/10/03

In re Application of	:	
Yoke Min SIN, et al.	:	
Serial No. 09/196,161	:	Group Art Unit: 1645
Filed: November 20, 1998	:	Examiner: N. Minnifield

For: RECOMBINANT VACCINE AGAINST INFECTIONS DISEASE IN FISH

RESPONSE

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D. C. 20231

Sir:

OK to enter 7/15/03 NM

This paper is submitted in response to the office action dated April 23, 2003. Reconsideration of the patentability of the claims of this application is solicited in view of the following comments and the declaration under the provisions of 37 CFR 1,132 filed herewith.

The outstanding action has withdrawn most of the rejections and objections that had previously been made. However, the important rejections have been maintained. The examiner has made these maintained rejections final. It is recognized that, after final rejection, the examiner has great latitude in either admitting or not permitting the introduction of further evidence. In this matter, it is urged that the circumstances are such that the declaration evidence submitted herewith should be entered and all of applicants' claims be found to be allowable in light of this evidence.

In the outstanding action, the examiner has rejected most of applicants' claims as being anticipated by the disclosure of the cited Lin et al. publication. This reference has previously been considered and its applicability traversed. This position of the applicants is respectfully repeated. The Lin et al. publication does not anticipate the instant claimed invention because the recombinant

fusion protein produced by an artificial DNA sequence from an immobilization antigen of, repeat I of Ich, of the instant invention is different from the overall sequence of the reference. In this regard, the examiner's attention is directed to the previously cited Clark et al. publication of 1992 that disclosed the sequence of the material of the Lin et al. article. Further, reference is here made to the attached declaration in which Dr. Sin clearly shows that the instant sequence is substantially different from the Clark et al./Lin et al. sequence.

It is accepted law that an anticipation rejection must be based on a single reference and that single reference must disclose each and every material feature of the claimed invention. In the instant claimed invention, the most important feature is the material of the vaccine, that is, the specific sequence of the claimed fusion protein. If the instant sequence is substantially different from the sequence of the prior art reference(s), the prior art reference(s) cannot support an anticipation rejection. Thus, in this case, the anticipation rejection must be withdrawn as not being supported by the evidence.

It is submitted that the declaration filed herewith does not submit new evidence. It is a recompilation of evidence that has always been in this application. Thus, the sequence of the instant invention has always been in this application and the sequence of the Lin et al. reference has always been in the Clark et al. publication, which too has always been in this application. The difference between the data in the attached declaration and the data that have always been in this application is merely in the manner in which these data have been presented. Prior to the filing of the instant declaration, the data were in two separate documents (actually, it could be considered that the data were in three separate documents if one considers the Clark et al. 1992 publication separately from the Lin et al. publication. In actuality, these documents should be considered as one reference since they supplement and clarify each other). The instant filed declaration merely assembles these disparate data into a single document and places the sequences side by side for easier evaluation. It is therefore urged that the examiner admit this declaration despite the fact that this application is under final rejection.

A review of the data in the attached declaration will clearly and easily show that the Clark et al. sequence is materially different than the instant Sin et al. sequence. The examiner's attention is

directed to the "Figure Legend" that appears at the end of the attachment to the declaration. Here, Dr. Sin states and specifically points out the different codons and the different nucleotides in the instant claimed fusion protein as compared to the Clark et al. sequence. There are 20 differences in the nucleotide sequences. These facts totally belie anticipation of the instant claimed composition by the Clark et al./Lin et al. composition. Further, there are ten (10) differences in the codons of the two sequences. These facts too totally belie any anticipation by the Lin et al./Clark et al. disclosed composition of the instant claimed composition.

Further, even assuming, *arguendo*, that one considers the patentability of the instant claimed sequence from an obviousness perspective, again using the Lin et al./Clark et al. sequence as the state of the prior art, there is still no basis for denying patentability of the instant claims. There are 30 substantial differences in the sequences of the reference as compared to the claimed sequence. Where, in the four f\corners of the reference is there any direction for making 30 material changes in the claimed sequence.

Obviousness must be considered from a consideration of the state of the prior art without reference to the instant specification. In the first place, in order to support a rejection based on obviousness, the examiner must first satisfy the inquiry as to whether the reference(s) establish *prima facie* obviousness. That is, taking the reference(s) for their face value, does the reference(s)' disclosure conform to the applicants' claims giving every consideration to the benefit of the reference(s). In this case, the answer must be NO! There is no disclosure of the instant claimed sequence. There is no disclosure of any reason why one of ordinary skill in this art would even think to make the 30 changes in the claimed sequence. Thus, the examiner has not satisfied the fundamental requirement of an obviousness rejection: that is that inherent in a single reference, or absolutely in a combination of the disclosures of several references is the instant claimed invention. Without satisfying that requirement, the rejection must fail before it even gets started.

Further, as has been explained many times before, the instant claimed fusion protein is produced by an artificial DNA sequence. The examiner has eschewed this feature of the invention saying that it is a process limitation and therefore is of no moment in considering the patentability

of the products being claimed. In the first place, the examiner is wrong in asserting that a process feature cannot give rise to the patentability of a product. If the product that is being made by the process described in the reference is different from the product that is being made by the process of the instant invention, that difference in the process is responsible for the difference in the product. The difference in the product may not be quantifiable sufficiently to differentiate it from the product disclosed in the prior art. That is not the case here, but it could be the case in some other circumstance. Under those circumstances, the difference in the process of making the claimed product is a very important part of characterizing the claimed product and so the difference in the process. Thus, the examiner's position on this point is respectfully traversed.

In this case, however, there are 30 differences between the claimed product and the product disclosed in the prior art. The fact that the claimed product is made by a different process could then be considered to be surplussage in the differentiation from the prior art. In fact, it may well be that the difference in the process of making the instant claimed product is what is responsible for the difference between the claimed product and the product of the prior art. In any case, whether the examiner places the emphasis on the 30 differences in the seque4nce of applicants' product or in the different process of making the claimed product, or in a combination of the two, the claimed product is sufficiently different from the state of the prior art to warrant patenting either from an anticipation or an obviousness perspective.

The instant fusion protein is produced by *E coli*. It could not be exactly the same as the protein of the Clark et al. reference although it has the same ability to agglutinate the ciliated protozoan. In the Lin et al article, it is stated, "...our laboratory has attempted to identify immunogens that by themselves stimulate protective immunity and might thus be used for the development of recombinant vaccines". That is not an original idea by Lin et al. Many workers prior to Lin et al. Have made that same suggestion. It is pointed out, however, that neither then Lin et al. group nor any other group has published any information on recombinant proteins developed for immobilizing antigen of the protozoan at issue here. This fully supports applicants' position that the prior art has no disclosure from which a vaccine as in the present invention can be created.

Claims 1, 3, 4 and 6-8 should be allowed.

The rejection of the patentability of claims 2 and 5 as being directed to subject matter that would have been obvious to a person of ordinary skill in this art has been considered and is respectfully traversed. The principal reference is the Lin et al. publication. The secondary references are the Clark et al and Smith et al. publications that have been cited by the examiner. The principal reference discloses a protein sequence that is substantially different (different in 30 distinct particulars) from the fusion protein being claimed herein. There is nothing in the secondary references, or in the primary reference itself, that would suggest these 30 changes to a person of ordinary skill in this art. If one looks at the primary reference without having the instant specification for a guide one does not see any means of modification to the end of producing a vaccine as in the instant case. Not only are claims 2 and 5 patentable because the claim that they depend from an independently patentable claim, but they are patentable in their own right as setting forth a composition that is unknown in the art and is not *prima facie* obvious from a consideration of the disclosures of the prior art.

In the absence of establishing a case of *prima facie* obviousness, the burden remains with the examiner to show why the claims do not present a patentable invention. The examiner has not satisfied this burden. Therefore, all of the instant claims should be allowed.

It is requested that, even if the examiner does not find applicants' claims to be allowable, she enter the enclosed declaration so that the application will be in better condition for appeal.

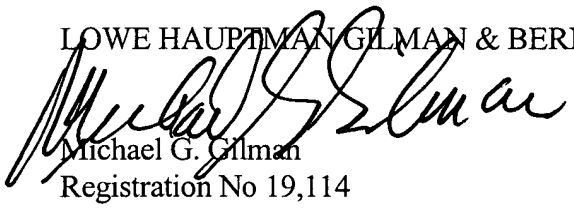
There is being filed herewith a supplemental Information Disclosure Statement submitting copies of the previously submitted references. Should the examiner require any additional information, she is requested to telephone the undersigned attorney.

The issues with the drawing have been noted. They will be corrected upon allowance of a claim.

It is urged that the examiner carefully reconsider her position and allow all of the instant claims.

Respectfully submitted

LOWE HAUPTMAN GILMAN & BERNER, LLP



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Enclosure: Declaration under 37 CFR 1.132
IDS

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